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ECONOMIC COMMISSION FOR EUROPE

SENIOR ADVISERS TO ECE GOVERNMENTS
ON SCIENCE AND TECHNOLOGY

INVENTORY OF EXISTING SAFETY GUIDELINES IN BIOTECHNOLOGY

MONOGRAPH

Information transmitted by the Government of Germany

SUMMARY OF SUBMISSION

1. The present submission which was prepared by the Federal Ministry of Health confines itself to a description of amendments most recently made in the Genetic Engineering Law. Therefore, it should be considered in conjunction with document ECE/SC.TECH./40/Add.14/Rev.2 of 26 April 1991.

2. The first amendment of the Genetic Engineering Law came into force in December 1993 due to the following major reasons:

(i) The arguments of industry and scientists were taken into account. The "unsurmountable bureaucratic burdens" on the development of a competitive German biotechnology industry had to be overcome;

(ii) The various different interpretations and executions of the Law needed to be harmonized between the Länder; and

(iii) The concerns of the European Commission about not implementing completely the EU Directives on the Contained Use of Genetically Modified micro-organisms (90/219 EEC) and on the Deliberate Release into the Environment of Genetically Modified Organisms (90/220/EEC) had to be met.

3. A draft proposal for a revision of the Law which was issued in March 1993 by the responsible Federal Ministry of Health was put forward for parliamentary discussion by the Cabinet in May 1993. At the same time, a list of proposed changes for the EU Directives was agreed. After debates within the Bundestag and the Bundesrat, a final agreement was reached in November 1993 on the following changes:

(i) Time periods are reduced for notifications and approvals of installations as well as operations using no- or low-risk organisms of class 1 and 2. The obligatory participation of the national scientific advisory board - the Central Commission for Biological Safety - is reduced to an appropriate level (paragraphs 8 to 12);

(ii) The administrative requirements for deliberate releases of genetically modified organisms are reduced (paragraphs 14(4) and 18(2);

(iii) The requirement of a public hearing for installations, where Type B operations with safe organisms of class 1 are performed, is deleted as well as for class 2 if not required by paragraph 10 of the federal emission-control law (paragraph 18(1);

(iv) The administrative requirements for the notification of an installation performing operations with class 1 organisms are streamlined following the one-door-one-key principle for other administrative requirements if necessary (paragraph 22(2) new);

(v) It is made clear that the direct application of genetically modified organisms (GMOs) to human beings does not come under the scope of this Law (paragraph 2(2) new); and

(vi) The term "placing in market" is newly defined to specify that it does not apply to the national and international exchange of GMOs between research organizations (paragraph 3(8).

4. The Federal Minister of Health provided the following comments: "A bureaucratic burden without gaining safety is not justified. Therefore, there was an urgent need to adapt the requirements of this Law of 1990 to the present knowledge as far as possible within the existing framework of the EU Directives. The politicians involved have demonstrated their willingness and ability to promote the key technology of genetic engineering. Now, it is up to science and industry to make use of this positive legal framework: successful basic research must be used faster and be turned more directly into marketing of products".

5. The amended Law improves the conditions for the application of biotechnology in research and industry but the safety issues concerning human health and the environment are not affected. Furthermore, the public's participation and

information rights are adequately taken care of.

LIST OF DOCUMENTS TRANSMITTED TO THE SECRETARIAT AND AVAILABLE FOR CONSULTATION UPON REQUEST

(a) The text of the first law to amend the Genetic Engineering Law of 16 December 1993

(b) The revised version of the Genetic Engineering Law of 16 December 1993

(c) A brochure of the Federal Ministry of Health concerning the revision of the Genetic Engineering Law

All documents are available in German only.